

MINUTES OF THE MEETING
OF THE
BOARD OF PHARMACY

September 12, 2005

ROLL CALL

Richard Zarek, R.P., Chair, called the meeting of the Board of Pharmacy to order at 8:00 a.m. in the Nebraska Room of the DoubleTree Guest Suites, 7270 Cedar Street, Omaha, Nebraska. Copies of the agenda were sent to Board members and other interested parties prior to the meeting. The following Board members answered the roll call:

Richard Zarek, R.P., Chairperson
C. Curtis Barr, R.P. Vice-Chairperson
Kevin Borchert, R.P., Secretary
Linda Labenz

Absent: Roger Kaczmarek, R.P.

A quorum was present and the meeting convened. Also present from the Department were: Becky Wisell, Section Administrator; Vonda Apking, Credentialing Coordinator; Tony Kopf, R.P., Ronald Klein, R.P., and Mike Swanda, R.P., Pharmacy Inspectors; Jeff Newman, Investigator and Michael Grutsch, Program Manager, from the Investigations Division; and Lisa Anderson, Assistant Attorney General.

REVIEW OF AGENDA

Additions, Modifications, Reordering and Adoption of Agenda

The Board requested that the following applicants be removed from the consent agenda for further discussion; Jeremy Popek, Eric Clausen, Jason Crandall, Shane Zoucha, and Diane Schwilke.

Labenz moved, seconded by Barr, to approve the agenda with the Chair having the authority to rearrange as needed. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

Adoption of the Consent Agenda

Labenz moved, seconded by Borchert, to approve the consent agenda as amended. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

(6) Disciplinary Information (Actions Taken And Pending)— Consent

Name	Actions Taken and/or Pending	Alleged Violation
Cieslik, Marsha.	Completed one year probation on 7-13-2005	Filled prescription for labetalol with glipizide.
Gehrig, Julie	Order to Cease & Desist Unlicensed Practice of Pharmacy 8-17-05	Obtained information from another pharmacy for purposes of a prescription transfer.
Goedeken, Gretchen	Completed two year probation on 7-18-05	Dispensed controlled substances to her husband without a valid prescription; falsified pharmacy records.

Kohll, Louis	Petition for Disciplinary Action 5-5-05 Amended Petition for Disciplinary Action 7-19-05 Voluntary Surrender in lieu of Discipline 8-11-05	Plead guilty to one federal count of mail fraud, a felony, for mailing a check to a closed-door contract distributor, to obtain pharmaceuticals for Unicare & diverting these drugs into the inventories of K.P. & H. retail pharmacies.
Potmesil, Howard Shannon	Petition for Disciplinary Action & Temporary License Suspension 6-30-05 Order for Temporary License Suspension 7-1-05 & Notice of Hearing	Misrepresentation of material facts in procuring a license, theft of pharmaceuticals from place of employment, possession of Ativan for own use without a prescription, admitted to hospital for manic-depression, reported to emergency room staff that he may do harm to himself or family.
Yung Orin	Order to Cease & Desist Unlicensed Practice of Pharmacy 8-16-05	Stored medications for home health patients under his nursing care at his home.

(7A) - Pharmacist Intern Applicants with Misdemeanor/Felony Convictions – Consent

(7B) – Pharmacist Reinstatement-More Than 1 Year Following Non-Disciplinary Revocation – Consent

(7C) – Wholesale Drug Distributor Application with Disciplinary Action in Another State – Consent

(21) – Proposed Changes to the Prescribers and Prescribing Authority Document

**INVESTIGATIONAL REPORTS, DISCIPLINARY REPORTS, AND CONTROLLED SUBSTANCES
AUDIT REPORTS—CLOSED SESSION**

Barr moved, seconded by Labenz, to close the session at 8:06 a.m. to receive investigational reports, disciplinary reports, and controlled substances audit reports. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

Barr recused himself from discussion at 11:13 a.m.

Barr re-joins the meeting at 11:16 a.m.

Zarek moved, seconded by Labenz, to reopen the session at 11:26 a.m. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

DISCIPLINARY INFORMATION – ACTIONS TAKEN/PENDING – CONSENT

APPROVAL OF MINUTES – JULY 25, 2005

Barr moved, seconded by Labenz, to wait to approve the July 25, 2005 minutes until the next meeting. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

REGULATIONS DEVELOPMENT

181 NAC 6 Cancer Drug Repository Program Regulations – Public Hearing Comments

The Board discussed the comment from Senator McDonald concerning the Cancer Drug Repository Regulations. Barr moved to approve the regulations as presented. The Board commented that they did not approve the current regulations. Barr withdrew his motion. Wisell explained that the Department has posted a list of participants on their website.

175 NAC 8 Regulations Governing Pharmacies – Update

Wisell informed the Board that the 172 NAC 8 Regulations Governing Pharmacies are waiting for the Governor to approve them.

172 NAC 128 Regulations Governing the Practice of Pharmacy - Update

Wisell explained to the Board that the 172 NAC 128 Regulations Governing the Practice of Pharmacy are being reviewed by the Attorney General's office and will still need to be approved by the Governor. Wisell informed the Board that the Department is hopeful that the regulations will be approved prior to December 1, 2005.

UPDATE ON LB 318 – PROPOSED LEGISLATION ON WHOLESALE DRUG DISTRIBUTION

Barr stated that he will provide an update at the next Board meeting. **Agenda Item: Update on LB 318 – Proposed Legislation on Wholesale Drug Distribution.**

FINAL REPORT OF RECOMMENDATIONS AND FINDINGS FROM THE 407 REVIEW ON PHARMACY TECHNICIANS

Zarek explained the final report of the review committee recommendations for pharmacy technicians. Zarek commented that a member of the committee was concerned about the mandatory reporting issue. The concern was that pharmacy technicians do not use their professional judgement therefore pharmacy technicians do not have enough knowledge of the laws. Zarek commented that this concern was discussed with the Department and there is a possibility that if pharmacy technicians are included in the ULL then there would be reporting requirements. Zarek explained that the Board would need to provide education to the pharmacists concerning mandatory reporting for pharmacy technicians. Joni Cover, Nebraska Pharmacists Association (NPA), noted that the NPA does not want to require mandatory reporting by pharmacy technicians. Zarek explained that the Board of Health 407 committee reviewed the final report on September 9, 2005, but lacked a quorum and could not vote.

DISCUSSION ON POSSIBLE PROBLEMS WITH CARING FOR REFUGEES FROM HURRICANE KATRINA

Borcher commented that he was involved with providing pharmacy services to approximately 160-170 Hurricane Katrina refugees. Walgreens, Methodist Hospital, and several other participants provided health services to the refugees. Wisell commented that the Department has made some exception for the licensees applying by trying to verify their information in some other manner.

UNIFORM LICENSING LAW (ULL) REWRITE – BOARD INPUT

Wisell explained that the NCR committee met on August 31, 2005, to discuss input received from the public meeting. Wisell commented that she has been meeting with an internal workgroup on the directions for changes from the NCR committee. There will be a public meeting held in North Platte and Omaha to receive comments on the revised draft before the end of September. Some of the changes to the draft included a clearer definition of endorsement and leaving the hearing before the Board for reinstatement after discipline. Anderson commented that the Attorney General's office supports keeping the hearing before the Board for reinstatements after discipline. Wisell also stated that the Department determined several issues where the word "approval" is going to be used in the ULL. The Department believes that the Boards should approve the following: 1) Continued competency requirements, 2) Requirements for issuing the license, 3) Requirements for renewing a license, 4) Educational programs, 5) Reinstatements, and 6) Grounds for unprofessional conduct. Other places where the word "advice" was used, the Department is looking at using the term "guidance", "consent", or "recommendation". Wisell explained that the ULL will increase the Board members to include another public member and if the Board wishes to increase their professional membership then they should place this change in their practice act. Borcher is in favor of increasing Board membership to five professional members and two public members. Labenz questioned whether Board members should be actively practicing the profession of pharmacy. Labenz stated that the Board's concerns with appointing professional members need to be given to the Board of Health. Other changes to the ULL

include indefinite revocation and deleting the letter of concern. Wisell commented that practice concerns could be disseminated through the newsletter. Barr mentioned that searching the ULL and the Pharmacy Practice Act for the use of the term “Healing Arts” and make sure that pharmacists are included in the definition.

Roger Brink, Department Legal joined the meeting at 12:46 p.m.

REGULATIONS DEVELOPMENT CON’T

172 NAC 129 Delegated Dispensing Regulations – Input Received

Shannon Anderson, Alegent Health, And Patricia Zieg, Attorney representing Apria Healthcare and the Nebraska Hospital Association, presented the suggested changes to the Delegated Dispensing regulations. The suggested changes address certain challenges that oxygen dispensers face in the draft regulations. Barr noted that their suggestion is to exempt oxygen dispensers from the regulations. The Board discussed that in order to exempt oxygen dispensers from the regulations there would need to be a statutory change. The Board questioned when would a statutory change be introduced. Ms. Zieg commented that the plan is to introduce statutory language in January 2006. The Board suggested having another stakeholders meeting before the next Board meeting on November 7, 2005. Borchert and Barr volunteered to attend the stakeholders meeting. **Action Item: Staff will arrange a stakeholders meeting. Agenda Item: 172 NAC 129 Delegated Dispensing Regulations – Input Received.**

Rose Bridge, Southwood Healthcare Affiliates, commented that delaying the approval of the regulations is putting a burden on those willing to accept the Delegated Dispensing regulations as written.

PRACTICE QUESTIONS

Repackaging Issues

Ron Hospodka presented a question regarding the repackaging of medication dispensed to patients in a long-term care facility to the Board at the July 25, 2005, meeting. The Board requested that it be on the agenda for this meeting for more discussion. Kopf commented that there can only be one dispensing pharmacy and the pharmacy providing the repackaging service would need to be identified. The Board commented that there is a record keeping issue rather than a labeling issue. Roseann Virgil, RN, Nebraska Healthcare Association questioned whether a contracting pharmacist for a long-term care facility may refuse to provide repackaging services. The Board commented that the contracting pharmacist could refuse to repack medication for a patient. Wisell asked whether medications that were repackaged could be identified in case of recalls of the medication. The Board stated that they still agreed with the answer that was given at the July 25, 2005, meeting. The Board suggested developing guidelines or pursuing a regulation change to address this issue.

Zarek asked that the Board introduce themselves to the students in attendance.

Faxed Prescriptions Issues

Roger Brink, Department Legal, commented that LB 382 amended Neb. Rev. Stat. §71-1,146.01 to include language for faxed or electronic transmitted prescriptions that are not signed by the practitioner to be treated the same as an oral medical order. Mr. Brink also stated that an agent can transcribe the prescription to written form and fax without the practitioner’s signature to the pharmacy and the pharmacist is no longer required to call for verification unless the pharmacist chooses to use his professional judgement. The faxed prescription must include all required information for a prescription. Zarek commented that the article he wrote for the newsletter will explain this change.

MD Signatures on Hard Copy Prescriptions

The Board’s opinion is that a nurse cannot sign the prescription for the prescriber.

Calculated Expiration Date

The Board discussed that hospitals repackage medications. The Board commented that hospitals are not governed by the Board, therefore the Board is unable to give a definitive answer. Borchert commented that the hospital he works for uses the USP Guidelines. The Board recommends that hospitals use either the USP Guidelines, the manufacturer's expiration date or one-year whichever is less.

Roger Brink, Department Legal left the meeting at 3:00 p.m.

APPLICATION REVIEW

Zarek explained the process of reviewing applications to the audience in attendance and shared the Board's concern with reviewing multiple applicants with misdemeanor/felony convictions.

Pharmacist Intern Applicants with Misdemeanor/Felony Convictions

Borchert moved, seconded by Barr, to request Eric Clausen to submit additional information to include the complaint, arraignment documents, journal entries, sentencing order, probation order and invite him to discuss this information during closed session at their November 7, 2005 meeting. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

Barr moved, seconded by Labenz, to request Jason Crandall to submit additional information to include his chemical dependency evaluation, proof of completing the diversion program, record of any other misdemeanor/felony conviction(s) and invite him to discuss this information during closed session at their November 7, 2005 meeting. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

Borchert moved, seconded by Labenz, to request a pre-licensure investigation on Jeremy Popek. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Abstained: Barr. Absent: Kaczmarek. Motion carried.

Labenz moved, seconded by Barr, to approve the issuance of a pharmacist registration to Diane Schwilke. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

Labenz moved, seconded by Barr, to invite Shane Zoucha to discuss his application with the Board during closed session at their November 7, 2005 meeting. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried.

UNIFORM LICENSING LAW (ULL) REWRITE – BOARD INPUT CON'T

Practice Act Changes

Wisell explained the changes to the Pharmacy Practice Act. The ULL will be requiring one new public member to be appointed, so if the Board would like to add a professional member this will be in a change in the language in the practice act. The Board suggested adding a professional member but were also concerned with staggering the start dates of the new member so four new members would not start at the same time. Wisell also explained the Department's decision to use the word "recommendation" for certain aspects of the practice instead of the word "advice". The Board commented on where they would like to see the word "recommendation", "consent" and "approval" throughout the practice act. Anderson commented that the Board of Pharmacy should request an Attorney General's opinion on the definition of the word "recommendation".

ALTERNATIVES FOR EXPANDING CE ACCEPTANCE

Barr explained that ACA certification programs include continuing education credits. Wisell asked how long the certificate is good for. Barr commented that the certificates are good for either five or seven years. Barr commented that he had submitted draft language previously. Wisell will bring Barr's draft language back to the Board at their next meeting. **Agenda Item: Draft Language on Accepting Certification as Meeting the Continuing Competency Requirements.**

COMMITTEE REPORTS

MPJE Committee

No report at this time. Kopf commented that there is another meeting scheduled for January 2006.

Tri-partite Committee on Internship

No report at this time.

Formulary Advisory Committee (FAC)

Reappointment of Board Designee to the Committee

Wisell explained that Allison Dering-Anderson, R.P. was up for reappointment to the FAC. Barr moved, seconded by Labenz, to reappoint Allison Dering-Anderson, R.P. Voting aye: Barr, Borchert, Labenz, Zarek. Voting nay: None. Absent: Kaczmarek. Motion carried. **Action Item: Staff to inform Joyce Novak of the Board's reappointment.**

NABP ISSUES

Report on the District V Meeting – Minneapolis, MN – August 12-14, 2005

Zarek commented that there was a good presentation on re-importation issues in Canada. Some patients have been affected, even died, because counterfeit drugs are being re-imported into Canada. The next District V meeting will be held in Winnipeg, Canada. The Board reminded Wisell to figure the cost of this trip into the 2007 budget.

Action Item: Wisell to figure cost of the District V meeting into the 2007 budget.

FPGEE, TOEFL, and TSE

Barr explained the reasoning behind accepting the TSE scores forever. The examinations an applicant has to take to receive the Foreign Pharmacy Graduate Equivalency Certification (FPGEC) from NABP are only given at certain times throughout the calendar year. Some applicants are unable to sit for the other examinations before their TSE score expires.

NABP Seeks ACPE Representative

No nominations for a representative at this time.

Newsletter

Zarek has written an article on the 2005 Legislation. The Board asked Mike Swanda to write an article about suggestions for pharmacies on inspections and controlled substances audit. **Action Item: Swanda will forward staff his article. Apking will prepare the articles and send them to NABP before September 30, 2005.**

ACPE REQUESTS COMMENTS ON DRAFT PHARM D STANDARDS AND GUIDELINES BY NOVEMBER 1, 2005

Barr commented that he did not have any comments to submit, because others have submitted similar comments.

NOMINATIONS FOR THE 2006 PAUL F. PARKER MEDAL FROM THE AMERICAN COLLEGE OF CLINICAL PHARMACY (ACCP)

No nominations at this time.

PROPOSED CHANGES TO THE PRESCRIBERS AND PRESCRIBING AUTHORITY DOCUMENT

The Board made revision to the document and requested that the document be reprinted in the newsletter. The Board suggested getting Ron Hospodka's permission to reprint the document.

FINANCIAL REPORT

Wisell explained to the Board that \$485,560.54 was transferred out of their fund and into the facility fund. Wisell also informed that Board that she will have a budget for them to review before the next Board meeting.

ACTION ITEMS

Wisell informed the Board that since Apking has been out of the office this was not updated. Apking will update this list and bring to the next Board meeting. **Action Item: Apking will update the Action Item list and bring to the November 7, 2005, Board meeting.**

CORRESPONDENCE AND GENERAL INFORMATION

The Board and staff wished Linda Labenz "Happy Birthday" tomorrow.

ADJOURNMENT

There being no further business, the meeting adjourned at 4:36 p.m.

Respectfully submitted,

(Signature on file with the Department)

Kevin Borchert, R.P., Secretary
Board of Pharmacy